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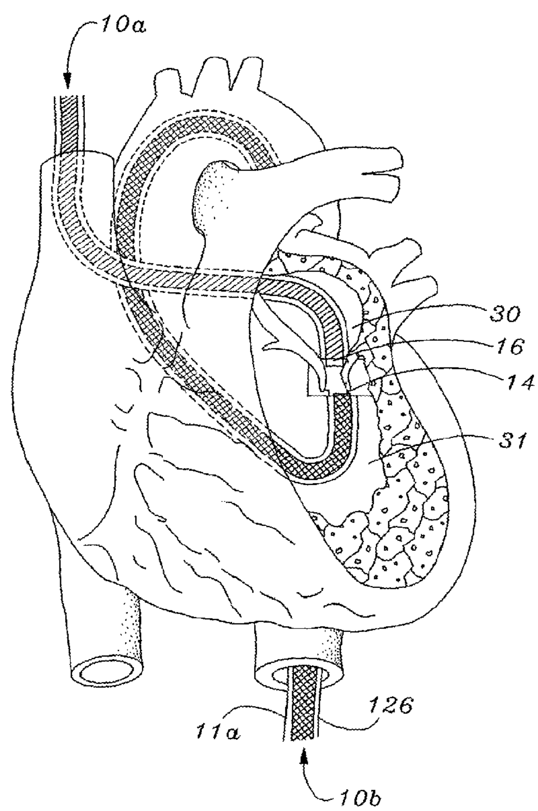
(54) Title: METHOD AND SYSTEM FOR TISSUE REPAIR USING DUAL CATHETERS



(57) Abstract: The present system is directed to a method and system to stabilize and repair tissue. At least two opposing devices may be used to stabilize and repair the tissue, with the two devices cooperatively engaging the tissue interposed therebetween. Stabilization may be accomplished by opposing force, vacuum force, or mechanical devices disposed at the distal portion of one or both devices. After the tissue has been stabilized, fasteners may be deployed into the tissue. Fasteners include sutures, clips, and staples. Also disclosed is a minimally invasive method of accessing tissue located within a body and conducting a repair of the area using the system disclosed herein.

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METHOD AND SYSTEM FOR TISSUE REPAIR USING DUAL CATHETERS

FIELD OF THE INVENTION

The present invention relates to the repair of tissue, and, more particularly, to a method and apparatus for the repair of tissue within the body of a patient by using a dual catheter system to stabilize the tissue, and if required, fasten the tissue portions together.

BACKGROUND OF THE INVENTION

In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers. The left and right atria and the left and right ventricles, each provided with its own one-way outflow valve. The natural heart valves are identified as the aortic, mitral (or bicuspid), tricuspid and pulmonary valves. The valves separate the chambers of the heart, and are each mounted in an annulus therebetween. The annuluses comprise dense fibrous rings attached either directly or indirectly to the atrial and ventricular muscle fibers. The leaflets are flexible collagenous structures that are attached to and extend inward from the annuluses to meet at coapting edges. The aortic and tricuspid valves have three leaflets, while the mitral and pulmonary valves have two.

Various problems can develop with heart valves, for a number of clinical reasons. Stenosis in heart valves is a condition in which the valves do not open properly. Insufficiency is a condition which a valve does not close properly. Repair or replacement of the aortic or mitral valves are most common because they reside in the left side of the heart where pressures and stressesare the greatest. In a valve replacement operation, the damaged leaflets are excised and the annulus sculpted to receive a replacement prosthetic valve.

In many patients who suffer from valve dysfunction, surgical repair (i.e., "valvuloplasty") is a desirable alternative to valve replacement. Remodeling of the valve annulus (i.e., "annuloplasty") is central to many reconstructive valvuloplasty procedures. Remodeling of the valve annulus is typically accomplished by

mplantation of a prosthetic ring (i.e. "annuloplasty ring") to stabilize the annulus and to correct or prevent valvular insufficiency that may result from a dysfunction of the valve annulus. Annuloplasty rings are typically constructed of a resilient core covered with a fabric sewing ring. Annuloplasty procedures are performed not only to repair damaged or diseased annuli, but also in conjunction with other procedures, such as leaflet repair.

Mitral valve regurgitation is caused by dysfunction of the mitral valve structure, or direct injury to the mitral valve leaflets. A less than perfect understanding of the disease process leading to mitral valve regurgitation complicates selection of the appropriate repair technique. Though implantation of an annuloplasty ring, typically around the posterior aspect of the mitral valve, has proven successful in a number of cases, shaping the surrounding annulus does not always lead to optimum coaptation of the leaflets.

More recently, a technique known as a "bow-tie" repair has been advocated. The bow-tie technique involves suturing the anterior and posterior leaflets together in the middle, causing blood to flow through the two side openings thus formed. This technique was originally developed by Dr. Ottavio Alfieri, and involved placing the patient on extracorporeal bypass in order to access and suture the mitral valve leaflets.

A method for performing the bow-tie technique without the need for bypass has been proposed by Dr. Mehmet Oz, of Columbia University. The method and a device for performing the method are disclosed in PCT publication WO 99/00059, dated January 7, 1999. In one embodiment, the device consists of a forceps-like grasper device that can be passed through a sealed aperture in the apex of the left ventricle. The two mitral valve leaflets meet and curve into the left ventricular cavity at their mating edges, and are thus easy to grasp from inside the ventricle. The mating leaflet edges are grasped from the ventricular side and held together, and various devices such as staples are utilized to fasten them together. The teeth of the grasper device are linearly slidable with respect to one another so as to align the

mitral valve leaflets prior to fastening. As the procedure is done on a beating heart, and the pressures and motions within the left ventricle are severe, the procedure is thus rendered fairly skill-intensive.

There is presently a need for an improved means for performing the bow-tie technique of mitral valve repair, preferably utilizing a minimally invasive technique.

SUMMARY OF THE INVENTION

The present invention provides a method and system for approximating tissue using at least two catheters. More particularly, the present invention discloses a method and system of approximating a number of devices and methods for stabilizing tissue and fastening or "approximating" a single portion or discretepieces of tissue through the use of at least two probes directed to the area of interest by at least one guidewire. The tissue of interest may be straight, curved, tubular, etc. For example, many of the embodiments of the invention disclosed herein are especially useful for joining two leaflets of a heart valve. The coapting edges of the leaflets thus constitute the "tissue pieces." In other contexts, the invention can be used to repair arterial septal defects (ASD), ventricular septal defects (VSD), and in cases involving patent foraman ovale. Additionally, the present invention may be used during valve replacement surgery, to deploy a plurality of valve repair devices. In sum, the present invention in its broadest sense should not be construed to be limited to any particular tissue pieces, although particular examples may be shown and disclosed.

The present invention includes a number of guidewire-directed devices and methods for both stabilizing the tissue pieces to be joined, and fastening them together. Some embodiments disclose only the stabilizing function, others only the fastening function, and still other show combinations of stabilizing and fastening devices. It should be understood that certain of the stabilizing devices may be used with certain of the fastening devices, even though they are not explicitly shown in joint operation. In other words, based on the explanation of the particular device, one of skill in the art should have little trouble combining the features of certain of

two such devices. Therefore, it should be understood that many of the stabilizing and fastening devices are interchangeable, and the invention covers all permutations thereof.

Furthermore, many of the fastening devices disclosed herein can be deployed separately from many of the stabilizing devices, and the two can therefore be deployed in parallel.

The guidewire-directed stabilizing and fastening devices of the present invention can be utilized, for example, in endoscopic procedures, beating heart procedures, or percutaneous procedures. In yet another embodiment the devices can be delivered into the heart through the chest via a thorascope. The devices can also be delivered percutaneously, via a catheter or catheters, into the patient's arterial system (e.g. through the femoral or brachial arteries). Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description.

Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description.

Brief Description of the Drawings

Figure 1 is a elevational view of a step in a valve repair procedure using the present invention;

Figure 1a is an elevational view of an embodiment of a vacuum based probe of the present invention;

Figure 1b is an elevational view of an embodiment of a vacuum based probe of the present invention disposing including vanes;

Figure 2 is an elevational view of an embodiment of a vacuum based probe of the present invention having a tapered nose and disposing vanes;

Figure 2a is an sectional view of a step in a valve repair procedure using the tissue stabilizer of Figure 2;

Figures 3a-3c are perspective views of several embodiments of vacuum-based tissue stabilizers having tissue separating walls;

Figures 3d and 3e are sectional views of two different vacuum port configurations for the tissue stabilizers shown in Figures 3a-3c, the stabilizers shown in operation;

Figure 4a is an elevational view of a first step in a valve repair procedure using a mechanical tissue stabilizer with linearly displaceable tissue clamps;

Figure 4b is an elevational view of a second step in a valve repair procedure using the tissue stabilizer of Figure 4a;

Figure 4c is a detailed perspective view of a clamp of the tissue stabilizer of Figure 4a extended to grasp a valve leaflet from both sides;

Figure 5a is a perspective view of a suture-based tissue fastener of the present invention having toggles;

Figure 5b is a sectional view of the suture-based tissue fastener of Figure 5a loaded into a delivery needle;

Figures 6a-6c are elevational views of several steps in a valve repair procedure using a tissue stabilizer of the present invention and the suture-based tissue fastener shown in Figure 5a.

Figure 7 is an elevational view of an alternative tissue stabilizing and fastening device;

Figures 8a-8c are sectional views of a tissue stabilizing and fastening device of the present invention having needles deployed by the retrograde probe on the ventricular side of the tissue being received by the antegrade probe;

Figure 9a is a perspective of a further tissue fastening device of the present invention comprising a staple-like tissue fastener in an open configuration;

Figure 9b is a perspective view of further tissue fastening device of the present invention comprising a staple-like tissue fastener in a closed configuration;

Figures 10a-10c are sectional views of several steps in a valve repair procedure using an exemplary tissue fastening device of the present invention for delivering the tissue staple of Figures 9a-9b;

Figure 11 is a perspective view of a completed valve repair procedure utilizing the tissue stabilizing and fastening device of Figures 10a-10c;

Figure 12 is an elevational view of an alignment mechanism of the present invention of the present invention;

Figures 13a-13b are sectional views of a wire-based steering mechanisms of the present invention;

Figures 14a-14b are sectional view of the steering sleeve based steering mechanism of the present invention;

Figure 15 is a sectional view of the steering balloon based steering mechanism of the present invention; and

Figures 16a-16c are sectional views of several steps in a tissue repair procedure using an exemplary sequential tissue repair device of the present.

DETAILED DESCRIPTION OF THE INVENTION

The method and system of the present invention is designed for use in the surgical treatment of bodily tissue. As those skilled in the art will appreciate, the exemplary guidewire-directed dual catheter tissue repair system disclosed herein is designed to minimize trauma to the patient before, during, and subsequent to the surgical procedure, while providing improved device placement and enhanced tissue stabilization. Additionally, the guidewire-directed dual catheter tissue repair system, by utilizing two separate and distinct probes that cooperatively interact, may be adapted to precisely deliver and deploy a plurality of tissue fasteners to an area of interest. For example, the present system may be utilized to repair mitral valve tissue by stabilizing the discrete tissue pieces and deploying a fastening device thereby coapting the tissue pieces. As those skilled in the art will appreciate, the present invention may similarly used to repair Arterial Septal Defects (ASD), Ventricular Septal Defects (VSD), and defects associated with Patent Foramen Ovale (PFO).

The present invention incorporates by reference many of the device features and various tissue fastening devices disclosed the applicant's pending U.S. application entitled "Minimally Invasive Mitral Valve Repair Method And Apparatus", application number 09/562406 filed May 1, 2000. Disclosed herein is a

detailed description of various illustrated embodiments of the invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention. The section titles and overall organization of the present detailed description are for the purpose of convenience only and are not intended to limit the present invention.

As those skilled in the art will appreciate, the present invention permits the operator to position at least two guidewire-directed probes within a body vessel and utilize the cooperative effects of the two positions and deploy a plurality of fastening devices to surrounding tissue. In the illustrated embodiment, the two probes comprise an antegrade probe positioned proximate to the superior or atrial portion of the mitral valve, and a retrograde probe positioned proximate to the inferior or ventricular portion of the mitral valve. It is anticipated as being within the scope of the present invention to utilize the present invention to perform a plurality of surgical procedures, and may deliver and deploy a plurality of tissue fastening devices to an intra-vascular area.

For example, the present device may be utilized to repair defects in the arterial septum. At least two guidewire-directed probes, one probe addressing the tissue from an antegrade position and the other probe addressing the tissue from a retrograde position, are used to stabilize the arterial septal tissue. Once stabilized, a fastening device maybe deployed to repair the defect. Similarly, the present invention maybe used to repair venticular septal defects, or defects relating to patent foramen ovale.

A. Exemplary Procedure Description

Figure 1 shows an embodiment of the present invention being utilized to repair a heart valve. More particularly, **Figure 1** shows a guidewire-directed antegrade probe **10a** and retrograde probe **10b** being used to stabilize and repair the tissue leaflets **14** and **16** of the mitral valve.

A first guidewire **12a,** capable of traversing the circulatory system and entering the heart, is introduced into the femoral vein of a patient (or, alternatively

the right jugular vein) through an endoluminal entry point. The first guidewire **12a** is advanced through the circulatory system eventually arriving at the heart. Upon arriving a the heart, the first guidewire **12a** enters the right atrium of the heart. The first guidewire **12a** is directed to traverse the right atrium and puncture the atrial septum, thereby entering the left atrium. The first guidewire **12a** is progressed through the mitral valve while the heart is in diastole thereby entering into the left ventricle. Thereafter the first guide wire **12a** is made to traverse through the aortic valve into the aorta and is made to emerge at the left femoral artery through a endoluminal exit point. This methodology is known to physicians skilled in interventional cardiology. Once first guide wire **12a** is positioned, a second guide wire **12b** similarly traverses the circulatory system and is positioned proximal to first guide wire **12a** using techniques familiar to those skilled in the art. The endoluminal entry and exit ports are dilated to permit entry of at least one probe. A protective sheath may be advanced within the venous area to protect the inner venular structure.

With guidewires **12a** and **12b** suitably anchored, the antegrade probe **10a** is attached to the guidewires **12a** and **12b** and advanced through the dilated guide wire entry point to a point proximal to the arterial cusp portion of the mitral valve. The distal portion of antegrade probe **10a**, having at least one vacuum port in communication with at least one vacuum lumen contained within at least one internal lumen of the probe, is positioned proximate the tissue leaflets **14** and **16** of the mitral valve. Once positioned, the antegrade probe **10a** may use vacuum force to capture and grasp the mitral tissue, grasp the tissue and deploy a fastening device, grasp and manipulate the mitral tissue, or grasp and manipulate the tissue to a desired positioned and deploy a fastening device. The manipulation or steering of the mitral tissue is accomplished by positioning the at least one vacuum port proximate the mitral tissue and activating the vacuum source. The mitral tissue will be forcibly retained by the vacuum force, thereby permitting the operator to steer or position tissue.

A retrograde probe **10b** is attached to at least one guidewire and introduced into the body through dilated guidewire exit point. The flexible retrograde probe **10b** is advanced through the body vessel, entering the heart through the aortic valve and progressing into the left ventricle. The distal portion of retrograde probe **10b** is proximal the ventricular portion of the of the mitral valve. The retrograde probe **10b** may include a distal portion having at least one vacuum port connected to at least vacuum lumen contained within at least one internal lumen, thereby permitting retrograde stabilization of tissue.

With the antegrade probe and retrograde probe suitably positioned, the external vacuum source connected to the antegrade probe, retrograde probe, or both, is activated, thereby permitting mechanical capture of the tissue. Upon successful tissue capture, a detachable fastening device mechanically retained either by antegrade probe **10a** or retrograde probe **10b**, or both, is forcibly deployed piercing the valve tissue and thereby mechanically joining the cusps of the mitral valve. These fastening devices may include self-closing fasteners, spring loaded fasteners, pre-formed fasteners, latching fasteners, and rotatably deployed fasteners.

To complete the procedure, the external vacuum source is deactivated, resulting in tissue release. The two probes are retracted through their individual entry points, and the two guidewires are removed. Finally, the endoluminary entry point and exit point are sutured.

B. Exemplary Guidewire Devices

Figure 1 shows a guidewire-directed dual catheter tissue stabilizer system comprising an antegrade probe **10a** and a retrograde probe **10b** of the present invention that is used to stabilize two tissue pieces **14** and **16**, respectively. The guidewires **12a** and **12b** may be formed of a single filament or a multi-filament wound system, and may be comprised of materials known to those skilled in the art of minimally invasive surgery, including, without limitation, a Nickel- Titanium (Ni Ti) compound, stainless steel #304, 304V, 312, and 316, or other suitable material. Likewise, the guidewires may be coated with a biologically-compatible lubricant or

with a biologically-compatible sealant such as polytetrafluoroethylene (PTFE). The guidewires should have sufficient structural flexibility and steerability to permit intraluminal positioning, while retaining sufficient structural integrity to position tissue stabilizers. Additionally, the guidewires may have a substantially circular profile, or, alternatively, may be shaped to provide a degree of axial control. For example, a wire incorporating a substantially octagonal profile would provide sufficient axial force to permit axial movement of the catheters along an axial arc.

During a procedure, a guidewire **12a** may be introduced to a body vessel in a plurality of manners, including, for example and without limitation, percutaneously, transapically, transatrially, or through a surgical incision proximate the area of interest. Guidewire **12a** is then positioned proximate to or traversing the area of interest. Once positioned and sufficiently anchored, a second guidewire **12b** may be similarly introduced to traverse the pathway established by guidewire **12a**, and likewise positioned within the mitral valve and suitably anchored. It should be understood that the present invention contemplates without limitation either a single guidewire or multiple guidewire approach. These guidwire or guidewires will direct and precisely position probes **10a** and **10b** proximate the area of interest. Upon completion of the procedure, the probes **10a** and **10b** and the guidewire (not shown) or guidewires **12a** and **12b** are removed from the body vessel.

C. Exemplary Tissue Stabilizing Devices

It should be understood that the antegrade and the retrograde probe disclosed herein cooperatively interact to provide stabilizing force to the tissue interposed therebetween. For example, the cooperative interaction may consist of the application of force to opposing surfaces of tissue interposed between the probes, vacuum force applied by either or both probes, and mechanical retaining devices, as detailed below, disposed on either or both probes. It is understood that both probes utilize at least one guidewire slidably attached to the distal portion of each probe to precisely position and align the probes. Furthermore, it is understood that the antegrade probe or the retrograde probe, or both, may apply the retentive force to

stabilize tissue. Additionally, tissue fastening device may be disposed about the proximal portion of the antegrade probe or the retrograde probe, or both, to approximate two pieces of tissue disposed between the opposing probes. A deployable alignment mechanism may be disposed about the distal portion of the antegrade probe or retrograde probe, or both, thereby ensuring a precise positioning of either or both probes with relation to the tissue.

Figure 1 shows two probes **10a** and **10b** of the present invention that uses a vacuum to stabilize two tissue pieces **14** and **16**, respectively. In this case, the procedure being conducted is a repair of a heart valve using an arterial probe **10a** and a ventricular probe **10b**. The at least two probes **10a** and **10b** may share common elements and will be generically described as probe **10**.

As shown in **Figure 1a**, the probe **10** comprises a cylindrical probe body **18** with at least one internal lumen (not shown) and having a flat distal portion **20** disposing at least two guidewire ports, **22a** and **22b**, and at least two vacuum ports **24a** and **24b**. It should be noted that the illustrated embodiment utilizes two guidwires, though the system may be operated using a single guidewire. The at least two guidewire ports, **22a** and **22b**, which are connected to at least two guidewire lumens (not shown), are disposed radially about the distal portion **20** of the probe **10**, and are substantially parallel to the longitudinal axis of at least one internal lumen (not shown). The at least two vacuum ports **24a** and **24b**, are in communication with an external vacuum source through the at least one internal lumen (not shown). The size of the ports, namely **24a** and **24b**, and magnitude of suction applied may be vary depending on the application. The spacing between the ports **24a** and **24b** should be sufficiently spaced so as to create independent suction regions. In this manner, one leaflet or the other may be stabilized with one of the ports, e.g. **24a**, without unduly influencing the other port, e.g. **24b**. In one example, the ports **24a** and **24b** have a minimum diameter of about 1/8 inch, and are spaced apart with a wall of at least 0.020 inches therebetween.

As shown in **Figure 1b**, the distal portion **20** may dispose a series of vanes, **25a** and **25b**, positioned proximate the vacuum ports **24a** and **24b**. The vane series, **25a** and **25b**, respectively, may be recessed from the distal portion **20**, thereby forming a tissue supporting structure when vacuum force is applied to pliable tissue. Preferably, the vanes **25a** and **25b** are recessed approximately 0.002 to .01 inches from the distal portion **20**.

The probe **10** desirably has a size suitable for minimally invasive surgery. In one embodiment probe **10** is part of a catheter based percutaneous delivery system. In that case probe **10** is a catheter tube having one or more lumens connecting vacuum ports **29a** and **29b** to the vacuum source or sources. The catheter would be long enough and have sufficient steerability and maneuverability to reach the heart valve from a peripheral insertion site, such as the femoral or brachial artery. One particular advantage of the present invention is the ability to perform valve repair surgery on a beating heart.

Figure 2 is illustrates an additional embodiment of the present invention utilizing a tapered distal portion of the probe. The probe distal portion **32** also includes a series of recessed vanes **34** connected to at least one internal lumen (not shown) to stabilize tissue. An additional port **36** may be used to deploy or receive a plurality of fastening devices.

Figure 2a shows an illustrative valve repair procedure using the probe **32** of **Figure 2** approaching the tissue from the arterial portion of the valve **30**, while additionally stabilizing the tissue with probe **10b** from the ventricular portion of the valve. The distal tip of the nose **36** is exposed to the ventricular **31** side of the leaflets **14** and **16**. Because of this exposure, various leaflet fastening devices can be delivered through the probe **34** to the ventricular side of the leaflets **14** and **16**, as will be detailed below. Likewise, a tissue fastening device may be deployed by probe **10b** through the leaflets, **14** and **16**, to the probe **34** positioned proximal to the arterial portion of the mitral valve. Interference with the stabilization process by guidewire **12** is negligible. Those skilled in the art will appreciate either the antegrade probe, the retrograde probe, or both, may utilize the tapered nose design detailed herein.

Figures 3a-3c show three vacuum-based tissue stabilizing probes having tissue separating walls. In **Figure 3a**, a tissue stabilizer **40** includes at least two guidewire ports **41a** and **41b** radially about the distal portion of the probe, having a flat distal face **42** having a pair of distally-directed tissue separating walls **44a** and

44b extending therefrom, and defining a gap **46** therebetween. The stabilizer **40** contains one or more lumens in communication with vacuum ports **48a** and**48b**, that open on both sides of the walls **44a** and **44b**. In addition, a fastener channel **50** opens at the distal face **42** between the walls **44a** and **44b**, and facing the gap **46** therebetween. The fastener channel **50** can be used to deliver tissue fasteners, as described below.

In **Figure 3b**, a tissue stabilizer **52** includes a flat distal face **54** disposing at least two guidewire ports **55a** and **55b**, and having a single distally-directed tissue separating wall **56** extending therefrom. The stabilizer **52** contains one or more lumens in communication with circular vacuum ports **58a** and **58b** that open on both sides of the wall **56**.

In **Figure 3c**, a tissue stabilizer **60** includes a flat distal face **62**, disposing at least two guidewire ports **63a** and **63b** radially position about distal face **62**, and having a single distally-directed tissue separating wall **64** extending therefrom. The stabilizer **60** contains one or more lumens in communication with semi-circular vacuum ports **66a** (not shown) and **66b** that open on both sides of the wall **64**. There are two such ports **66a** (not shown) and **66b**, one on each side of each wall **64**.

Figures 3d and **3e** show two different vacuum port configurations for the tissue stabilizers **40**, **52**, or **60** shown in **Figures 3a-3c**. As mentioned above, the stabilizers **40**, **52**, or **60** may have one or more lumens in communication with one or more ports. In Figure **3d**, two lumens **68a** and **68b** provide separate suction control to the associated ports. Thus, one tissue piece **70a** is seen stabilized by the right-hand vacuum port, while the left-hand port is not operated. Alternatively, a single lumen **72** in communication with two vacuum ports is seen in **Figure 3e**, and both tissue pieces **70a**, **70b** are stabilized simultaneously. In both these views, the tissue separating wall **74** is shown between the tissue pieces to be joined. Fastening devices can thus be delivered via the wall **74**, or through a gap formed for that purpose, such as the gap **46** and fastener channel **50** seen in**Figure 3a**.

Figures 4a-4c show a mechanical tissue stabilizer **80** with a four-part, linearly displaceable tissue clamp **82**, disposing at least two guidewire ports **81a** and **81b** (not shown), respectively, positioned radially about the distal portion of the stabilizer **80**. On each side, a lower clamp **84** is separated from an upper clamp **86** and inserted between two tissue pieces (in this case valve leaflets **14** and **16**). As the lower and upper clamps **84**, **86** are brought together, as seen in **Figure 4b**, they physically clamp and stabilize the leaflet **16**. Small teeth **88** on the clamps **84** and **86** may be provided for traction. The clamps **84** and **86** on each side are individually actuated to enable grasping of one leaflet at a time. Once the tissue has been suitably captured by antegrade probe **80** an retrograde probe (not shown) is utilized to deploy a fastening device to the captured tissue.

As stated above, the dual catheter system disclosed herein contemplates utilizing the probes disclosed above in a cooperative manner. As those skilled in the art will appreciate, various arterial probes may be used with various ventricular probes, thereby providing a dual catheter system capable of customization dependant on need. For example, an arterial probe having a tapered nose may be used with a ventricular probe having a flat distal portion. Alternatively, an arterial probe having a flat distal portion may be utilized with a ventricular probe having a tapered nose. As those skilled in the art will appreciate the system may be easily tailored accordingly.

D. Exemplary Tissue Fasteners

As stated in the previous sections, the present invention contemplates using at least one guide wire to direct and position at least two co-operatively functioning probes to an area of interest. In a preferred embodiment, at least two probes, each disposing at least two guidewire ports proximate to the distal portion thereof, would be directed to an area of interest by at least two guidewires. It should be understood that the present invention discloses using at least two guidewire-directed probes simultaneously to perform a surgical therapeutic procedure. The following sections disclose exemplary tissue fasteners capable of deployment with the guidewire-

directed dual catheter system of the present invention. The figures associated with the following sections are intended to illustrate novel fastening systems. As such, only one catheter may be illustrated, but a second catheter is assumed. Likewise, the following systems employ at least one guidewire and at least two guidewire ports disposed proximal the distal portion of the probes. To permit clear illustration of the novel fastening systems disclosed herein the guidewire or guidewire and guidewire ports may not be illustrated in the following figures, but should be assumed included.

1. Exemplary Suture-Based Tissue Fasteners

Figure 5a illustrates a suture-based tissue fastener **90** of the present invention including toggles **92** secured to the end of suture threads **94**. **Figure 5b** is a sectional view through a needle **96** used to deliver the tissue fastener **90**. Specifically, the toggle **92** and suture thread **94** is seen loaded into the lumen of the needle **96**, and a pusher **98** is provided to urge the tissue fastener **90** from the distal end thereof. The fastener **90** maybe deployed by the antegrade probe, the retrograde probe, or both.

Figures 6a-6c depict several steps in a valve repair procedure using the tissue fasteners **90** shown in **Figure 5a**. A probe, such as the probe **10** seen in **Figure 1** having vacuum ports for tissue stabilization and guidewire ports positioned radially about the distal portion of probe **10**, provides lumens for two of the needles **96** of **Figure 5b**. The lumens with the vacuum ports may receive the needles **96** or additional lumens may be provided. The sharp ends of the needles **96** pierce the leaflets, and the pushers **98** are displaced (separately or in conjunction) to deploy the tissue fasteners **90**. After the needles **96** are retracted, the toggles **92** anchor the tissue fasteners **90** on the ventricular **31** side of the leaflets. The suture threads **94** are then tied off on the atrial **30** side to secure the leaflets **14** and **16** together, as seen in **Figure 6c**. The retrograde probe used to stabilize the tissue is not shown to permit clear illustration of the novel fastening device. As with all system disclosed

herein, simultaneous use of an antegrade probe and retrograde probe is contemplated.

Figure 7 illustrates an alternative tissue stabilizing and fastening device **108** having a pointed nose with two concave faces **110** in which the vacuum ports are located. The device **108** functions as described above, with a fastener deliver needle shown in phantom having pierced the left leaflet **14**. A retrograde probe (not shown) may be adapted to receive the fastening device **108** as well as stabilize the tissue.

Figures 8a-8c illustrate a tissue stabilizing and fastening device **130a-b** having needles **132** deployable on a blind side of the tissue by the retrograde probe **130b**. A common suture thread **134** connects the needles **132** and is used to secure the tissue pieces **714** and **16** together. Thus, as seen in the sequence of**Figures 8a–8c**, the needles **132** are first advanced to a position proximate the tissue pieces **14** and **16** and deployed outboard of the distal tip of the retrograde probe 130b. Once positioned, the needles are advanced through the tissue, as in**Figure 8a**, to cause the needles **132** to pierce the tissue pieces **14** and **16**. The two needles **132** are then disengaged from the device **130b**, and each other, as in **Figure 8b**, and antegrade probe **130a** captures the needles **132** from the pieces **14** and **16**, leaving the connected suture joining the two pieces **14** and **16** (**Figure 8c**). The suture **132** can then be tied off, or otherwise secured on the upper side of the tissue pieces **14** and **16**.

2. Exemplary Staple and Clip-Type Fasteners

Figure 9a shows an exemplary tissue staple **280** for joining two tissue pieces in an open configuration. The staple **280** includes a bridge portion **282** and four gripping arms **244**, two on each side. The gripping arms **284** are initially curled in a semi-circle upward from the plane of the bridge portion **282** and terminate in sharp points approximately in the plane of the bridge portion **282**. **Figure 9b** shows the staple **280** when closed, with the gripping arms **284** curled underneath the plane of the bridge portion **282** toward each other.

Figures 10a-10c illustrate several steps in a valve repair procedure using an exemplary tissue fastening device **290** for delivering the tissue staple **280**. As with the previous embodiments, a retrograde probe (not shown) is utilized to stabilize the tissue prior to and during deployment of the fastening device. Additionally, the retrograde probe (not shown) may be used as an anvil or stop-body to assist in closing the fastener. The device **290** includes a probe **292** with an internal lumen **294** within which a pusher **296** is slidable, and having at least two guidewire ports (not shown) positioned radially about the distal portion of probe. A stop member **298** is also provided underneath the bridge portion **282** of the staple **280** to prevent displacement of the bridge portion **282** toward the leaflets **22**. The probe is positioned proximate the tissue under repair. After stabilizing the leaflets **22**, the pusher **296** displaces downward which causes the staple **280** to undergo a plastic deformation from the configuration of **Figure 10a** to that of **Figure 10b**. The sharp points of the gripping arms **284** pass through the leaflets **22** and anchor the staple **280** therein. Finally, the stop member **298** is disengaged from under the bridge portion **282**, and the device **290** is retracted.

Figure 11 illustrates the use of a tissue stabilizing and fastening device **300** for deploying the staple **280** of **Figure 9**. The device **300** is quite similar to the device **290** of **Figure 10,** with an exemplary stabilizing means shown in the form of vacuum chamber(s) **302** on each side of the staple deployment mechanism.

The present invention may be embodied in other specific forms without departing from its spirit, and the described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the claims and their equivalents rather than by the foregoing description.

E. Exemplary Probe Alignment Devices

An additional embodiment of the present invention includes alignment mechanisms which may be affixed to the probe to precisely position a probe proximate within a body vessel. Those skilled in the art will appreciate the use of an

alignment device in addition to the guidewire or guidewires disclosed above provides an inherently redundant alignment scheme, thereby permitting a more precise positioning of the probe relative to the area of interest.

Figure 12 shows an antegrade probe of the antegrade and retrograde probe system of the present invention that uses a vacuum to hold two tissue pieces **514** and **516,** respectively. In this case, the tissue pieces are heart valve leaflets, **514** and **516**, and a valve repair procedure using an arterial probe **512a** and a ventricular probe (not shown). Probes **512a** and **512b** will hereinafter be generically described as probe **512**. As shown in **Figure 12**, the probe **512** comprises a cylindrical probe body **518** with at least one internal lumen (not shown) and having a tapered distal portion **520** disposing at least one guidewire port (not shown) and at least one vacuum port. **524**. At least one deployable alignment mechanism **523** is positioned proximate the probe distal portion **520** and are in communication with the handpiece (not shown) by a deployment conduit (not shown) positioned in at least one internal lumen (not shown) contained within probe **512**. Once the probe **512** is positioned proximate to the tissue **514** and **516**, respectively, the deployable alignment mechanism **523** is deployed and interacts with the surrounding tissue. The external vacuum source (not shown) is then activated. The at least one vacuum port **524** stabilizes tissue pieces **514** and **516**. Upon completion of the procedure, deployable tissue fasteners are retracted to facilitate removal of the probe **512** While **Figure 12** shows the deployable alignment mechanism disposed on an antegrade probe, either the antegrade probe, retrograde probe, or both, may include deployable alignment devices.

F. Exemplary Steering Devices

The present invention discloses a guidewire-directed system for repairing body tissue. Use of guidewire-directed flexible antegrade and retrograde catheters permits positioning of the devices proximal the tissue under repair. Locating the device proximate tissue under repair may be facilitated by supplemental steering mechanisms capable of permitting the probes to traverse acute angles. Several

embodiments detailing a plurality of steering mechanisms are disclosed herein. The steering devices disclosed herein permit positioning of the antegrade catheter, retrograde catheter, or both, should supplemental steering mechanisms be required.

1. Steering Wire Approach

Figures 13a-13b show a mitral valve procedure being performed with the present invention. Antegrade probe **530a** is positioned proximate the arterial portion of the mitral tissue **532a** and **532b** by guidewires **534a** and **534b**. The retrograde probe **530b** is positioned proximate the ventricular portion of the mitral tissue **532a** and **532b**, and is similarly directed by guidewires **534a** and **534b**. Retrograde probe **530b** further disposes a steering conduit **536** which is connected to probe **530b** proximate the distal portion and which is in communication with the operator via at least one internal lumen (not shown) through a steering conduit port positioned on probe **530b**. The steering conduit **536** may be manufactured from a plurality of materials including a Nickel- Titanium (Ni Ti) compound, stainless steel #304, 304V, 312, and 316, or other suitable material.

2. Steering Sleeve Approach

Figures 14a-14b show a mitral valve procedure being performed by the present invention. Antegrade probe (not shown) is positioned proximate the arterial portion of the mitral tissue **542a** and **542b** by guidewires (not shown). The retrograde probe **540b** is positioned proximate the ventricular portion of the mitral tissue **542a** and **542b**, and is similarly directed by the guidewires. Retrograde probe **540b** further disposes a steering sleeve **546** containing an actuated support **548** which is connected a steering sleeve conduit **550** which is positioned within an internal lumen located probe **540b**. The probe **540b** and steering sleeve conduit are positioned proximate the tissue under repair. Once positioned probe **540** is advanced while the steering sleeve conduit **546** is held stationary. Advancement of the probe **540** results in extension of the actuated support **548** thereby positioning probe **540b** m more proximate the tissue under repair.

3. Steering Balloon Approach

Figure 15 shows a mitral valve procedure being performed by the present invention. Antegrade probe (not shown) is positioned proximate the arterial portion of the mitral tissue **552a** and **552b** by guidewires (not shown). The retrograde probe **554b** is positioned proximate the ventricular portion of the mitral tissue **552a** and **552b**, and is similarly directed by the guidewires. Retrograde probe **554b** further disposes at least one biasing joint containing at least one balloon which is connected to an inflation conduit (not shown) positioned within an internal lumen located probe **554b**. **Figure 15** shows a probe **554b** disposing 3 biasing joints **556a, 556b, and 556c**, each containing a steering balloon **558a, 558b, and 558c**, respectively. The probe **554b** is positioned proximate the tissue under repair. Once positioned, steering balloons **558a, 558b**, and **558c** are inflated thereby articulating the distal portion of the probe **554b** at an angle proximate the tissue.

G. Sequential Tissue Stabilization

The present invention may be adapted to sequentially stabilize a portion of tissue and deploy a tissue fastening device therein. As shown in**Figure 16a**, a first antegrade probe **564a** is advanced along at least one guidewire **562** to a position proximate the tissue to be repaired **566a** and **566b**. The first antegrade probe **564a** comprises a vacuum port **568** in fluid communication with a vacuum lumen **570** and a tissue fastening device **572** located within the probe **564a**. The tissue fastening device **572** may include fastener deployment mechanisms and fasteners disclosed above. A retrograde probe **564b**, which is used to position and stabilize the antegrade probe, is advanced along the at least one guidewire **562** to a position proximate the retrograde portion of the tissue. With the probes **564a** and **564b** positioned, a single portion of tissue **566a** is captured by the vacuum port **568** disposed on the first antegrade probe **564a.** A fastening device **572a** is deployed through the single portion of tissue **566a**. The first antegrade probe **564a** disengages the tissue **566a** and the retrograde probe **564b**, and is thereafter removed. **Figure 16b** shows a second antegrade probe **564c** comprising a vacuum port **574** in fluid

communication with a vacuum lumen **576**, and a tissue fastening device **572b** located within the probe **564c** is advanced to a position proximate the tissue **566a** and **566b**. Like the first antegrade probe **564a,** the second antegrade probe **564c** is adapted to engage the retrograde probe **564b**, and deploy a tissue fastener. Once the probes are positioned, the vacuum port **574** disposed on the second retrograde probe **564c** captures tissue portion **566b**. A tissue fastener **572b** is deployed into the tissue. The second antegrade probe **564c** disengages the tissue **566b**, and the second antegrade probe **564c** and retrode probe **564b** are removed. As shown in **Figure 16c**, the tissue fastening device is joined, for example, by tying, thereby repairing the tissue. Like the previous embodiments the probes **564a**, **564b**, and **564c** may include additional internal lumens.

In closing, it is noted that specific illustrative embodiments of the invention have been disclosed hereinabove. However, it is to be understood that the invention is not limited to these specific embodiments. Accordingly, the invention is not limited to the precise embodiments described in detail hereinabove. With respect to the claims, it is applicant's intention that the claims not be interpreted in accordance with the sixth paragraph of 35 U.S.C. § 112 unless the term "means" is used followed by a functional statement. Further, with respect to the claims, it should be understood that any of the claims described below can be combined for the purposes of the invention.

What is claimed is:

1. A system for performing a surgical procedure within a blood vessel, comprising:

at least one guidewire, said guidewire inserted into a body vessel; and

an antegrade probe having a distal portion, said antegrade probe comprising at least one antegrade guidewire lumen, said antegrade guidewire lumen terminating in at least one guidewire port, said at least one guidewire port positioned radially about said antegrade distal portion substantially parallel to the longitudinal axis of said antegrade probe;

a retrograde probe having a distal portion, said retrograde probe comprising at least one retrograde guidewire lumen, said retrograde guidewire lumen terminating in at least one guidewire port, said at least one retrograde guidewire port positioned radially about said retrograde distal portion substantially parallel to the longitudinal axis of said retrograde probe and co-aligned with said antegrade probe; and

at least one of said antegrade probe and said retrograde probe further comprising at least one lumen.

2. The system of claim 1, wherein said antegrade probe and said retrograde probe are placed over said guidewire so that said guidewire resides within said at least one antegrade guidewire port and said at least one retrograde guidewire port and wherein said at least one retrograde guidewire port is co-aligned with said at least one antegrade guidewire port.

3. The system of claim 1, further comprising a second guidewire and wherein said antegrade probe comprises a first antegrade guidewire lumen terminating in a first antegrade guidewire port and a second antegrade guidewire lumen terminating in a second antegrade guidewire port and said retrograde probe comprises a first retrograde guidewire lumen terminating in a first retrograde

guidewire port and a second retrograde guidewire lumen terminating in a second retrograde guidewire port.

4. The system of claim 3, wherein said first guidewire resides within said first antegrade guidewire lumen and said first retrograde guidewire lumen and said second guidewire resides in said second antegrade guidewire lumen and said second retrograde guidewire lumen to align said distal portion of said antegrade probe with said distal portion of said retrograde probe.

5. The system of claim 1, wherein said antegrade probe and said retrograde probe are each engageable with one of the two pieces of tissue, to stabilize the tissue pieces.

6. The system of claim 5, wherein said antegrade probe and retrograde probe are mutually engageable with the two pieces of tissue to stabilize the tissue pieces interposed therebetween.

7. The system of claim 1, wherein said at least one lumen comprises a vacuum lumen.

8. The system of claim 7, wherein said at least one vacuum lumen terminates in at least one vacuum port at said distal portion of said antegrade probe, thereby enabling the grasping and manipulation of tissue.

9. The system of claim 7, wherein said at least one vacuum lumen terminates in at least one vacuum port at said distal portion of said retrograde probe, thereby enabling the grasping and manipulation of tissue.

10. The system of claim 1, wherein at least one of said distal portion of at least one of said antegrade probe and said retrograde probe is substantially perpendicular to said longitudinal axis of said antegrade or retrograde probe.

11. The system of claim 1, wherein said distal portion of at least one said antegrade probe and said retrograde probe is tapered.

12. The system of claim 1, further comprising at least one tissue fastener at the distal end of either said retrograde probe or said antegrade probe.

13. The tissue fastener of claim 12, wherein said tissue fastener is a suture-based tissue fastener.

14. The tissue fastener of claim 12, wherein said tissue fastener is a clip.

15. The tissue fastener of claim12, wherein said tissue fastener is a staple.

16. The system of claim 12, wherein the other one of said antegrade probe and retrograde probe further includes a tissue fastener receiver, said receiver providing cooperative stabilization of tissue while affixing said tissue fastener.

17. The system of claim 1, wherein said at least one lumen comprises a tissue fastening lumen.

18. The system of claim 17, further comprising at least one tissue fastener at the distal end of either said retrograde probe or said antegrade probe.

19. The system of claim 18, wherein said tissue fastener is a needle and suture.

20. A system of claim 1, wherein at least one of said antegrade probe distal portion and said retrograde probe distal portion disposes at least one deployable alignment mechanism.

21. A deployable alignment mechanism of claim 20, comprising:

at least two alignment arms flexibly attached to the distal portion of at least one of said antegrade probe and said retrograde probe;

a deployment conduit operably connected to said at least two alignment arms;

said deployment conduit attached to a deployment actuator;

said at least two alignment arms having a retracted position wherein said arms are located proximal to the distal portion of at least one of said antegrade probe and said retrograde probe;

said at least two alignment arms having a deployed position wherein said arms are extended radially from said distal portion of at least one of said antegrade probe and said retrograde probe; and

said retracted and deployed positions achieved through manipulation of said deployment actuator.

22. The system of claim 21, wherein said at least one lumen comprises an alignment mechanism deployment lumen.

23. The system of claim 1, wherein at least one of said antegrade probe and retrograde probe have sufficient length, steerability and maneuverability to reach the tissue from a peripheral insertion site.

24. The peripheral insertion site of claim 23, wherein the peripheral insertion site is the femoral artery.

25. The peripheral insertion site of claim 23, wherein the peripheral insertion site is the brachial artery.

26. The system of claim 1, further comprising a steering mechanism located proximate to said distal portion of at least one of said antegrade probe and said retrograde probe.

27. The steering mechanism of claim 26, further comprising a steering conduit attached to said distal portion of at least one of said antegrade probe and said retrograde probe, said steering conduit in communication with an operator through one of said at least one antegrade lumen and said at least one retrograde lumen.

28. The system of claim 1, further comprising at least one echogenic member at or near the distal portion of one of said antegrade probe and said retrograde probe to enhance echo visualization.

29. The system of claim 1, further comprising a polymer coating which can be wholly or selectively applied at or near the distal portion of one of said antegrade probe and said retrograde probe to enhance echo visualization.

30. A system for repairing tissue, comprising:

at least one guidewire, said guidewire inserted into a body vessel; and

an antegrade probe having a distal portion, said antegrade probe comprising at least one antegrade guidewire lumen, said antegrade guidewire lumen terminating in at least one guidewire port, said at least one guidewire port positioned radially about said antegrade distal portion substantially parallel to the longitudinal axis of said antegrade probe;

a retrograde probe having a distal portion, said retrograde probe comprising at least one retrograde guidewire lumen, said retrograde guidewire lumen terminating in at least one guidewire port, said at least one retrograde guidewire port

positioned radially about said retrograde distal portion substantially parallel to the longitudinal axis of said retrograde probe and co-aligned with said antegrade probe; and

at least one of said antegrade probe and said retrograde probe further comprising at least one vacuum lumen.

31. A system for repairing tissue, comprising:

at least one guidewire, said guidewire inserted into a body vessel; and

an antegrade probe having a distal portion, said antegrade probe comprising at least one antegrade guidewire lumen, said antegrade guidewire lumen terminating in at least one guidewire port, said at least one guidewire port positioned radially about said antegrade distal portion substantially parallel to the longitudinal axis of said antegrade probe;

a retrograde probe having a distal portion, said retrograde probe comprising at least one retrograde guidewire lumen, said retrograde guidewire lumen terminating in at least one guidewire port, said at least one retrograde guidewire port positioned radially about said retrograde distal portion substantially parallel to the longitudinal axis of said retrograde probe and co-aligned with said antegrade probe;

at least one of said antegrade probe and said retrograde probe further comprising at least one vacuum lumen; and

at least one tissue fastener at the distal end of either said retrograde probe or said antegrade probe.

32. The tissue fastener of claim 31, wherein said tissue fastener is a suture-based tissue fastener.

33. The tissue fastener of claim 31, wherein said tissue fastener is a clip.

34. The tissue fastener of claim 31, wherein said tissue fastener is a staple.

35. The system of claim 31, wherein the other one of said antegrade probe and retrograde probe further includes a tissue fastener receiver, said receiver providing cooperative stabilization of tissue while affixing said tissue fastener.

36. A system for repairing tissue, comprising:

at least one guidewire, said guidewire inserted into a body vessel; and

an antegrade probe having a distal portion, said antegrade probe comprising at least one antegrade guidewire lumen, said antegrade guidewire lumen terminating in at least one guidewire port, said at least one guidewire port positioned radially about said antegrade distal portion substantially parallel to the longitudinal axis of said antegrade probe;

a retrograde probe having a distal portion, said retrograde probe comprising at least one retrograde guidewire lumen, said retrograde guidewire lumen terminating in at least one guidewire port, said at least one retrograde guidewire port positioned radially about said retrograde distal portion substantially parallel to the longitudinal axis of said retrograde probe and co-aligned with said antegrade probe;

at least one of said antegrade probe and said retrograde probe further comprising at least one vacuum lumen.; and

a steering mechanism located proximate to said distal portion of at least one of said antegrade probe and said retrograde probe.

37. The steering mechanism of claim 36, further comprising a steering conduit attached to said distal portion of at least one of said antegrade probe and said retrograde probe, said steering conduit in communication with an operator through one of said at least one antegrade lumen and said at least one retrograde lumen.

38. A method of stabilizing tissue, comprising:

delivering an antegrade probe to a position antegrade to the tissue;

delivering a retrograde probe to a postion retrograde to the tissue;

aligining said first probe and said second probe longitudinally;

using one or more of said first and said second probes to stabilize the tissue; and

using one or more of said first and said second probes to fasten the tissue.

39. The method of claim 38 wherein said antegrade probe and said retrograde probe are used simultaneously to provide cooperative support to the tissue interposed therebetween.

40. The method of claim 38, wherein all of the steps of the method are completed without arresting the heart.

41. The method of claim 38, further comprising the steps of:

delivering a guidewire through an entry point and passing said guidewire through the venous system and the into the left atrium;

using said guidewire to pierce the atrial septum and bringing said guidewire through the mitral valve to the right ventricle, exiting the heart through the aortic valve and aorta, and exiting the body through a exit point;

advancing said antegrade probe over said guidewire through the entry point and delivering said antegrade probe antegrade to the mitral valve; and

advancing said retrorade probe over said guidewire through the exit point and delivering said retrorade probe retrograde to the mitral valve.

42. The method of claim 38 further comprising the step of aligning said antegrade probe and said retrograde probe to interact with and to provide stabilizing support to the tissue.

43. The method of claim 38, further comprising manipulating at least one of the leaflets of the mitral valve disposed proximate to at least one of said antegrade probe and said retrograde probe.

44. The method of claim 38, wherein said tissue is mitral valve leaflet tissue.

45. The method of claim 38, wherein one or more of said first and said second probes utilizes a suture-based fastener to fasten the tissue.

46. The method of claim 38, wherein one or more of said first and said second probes utilizes a clip to fasten the tissue.

47. The method of claim 38, wherein one or more of said first and said second probes utilizes a staple to fasten the tissue.

48. The method of claim 38, wherein at least one of said antegrade probe and said retrograde probe is delivered through a femoral artery.

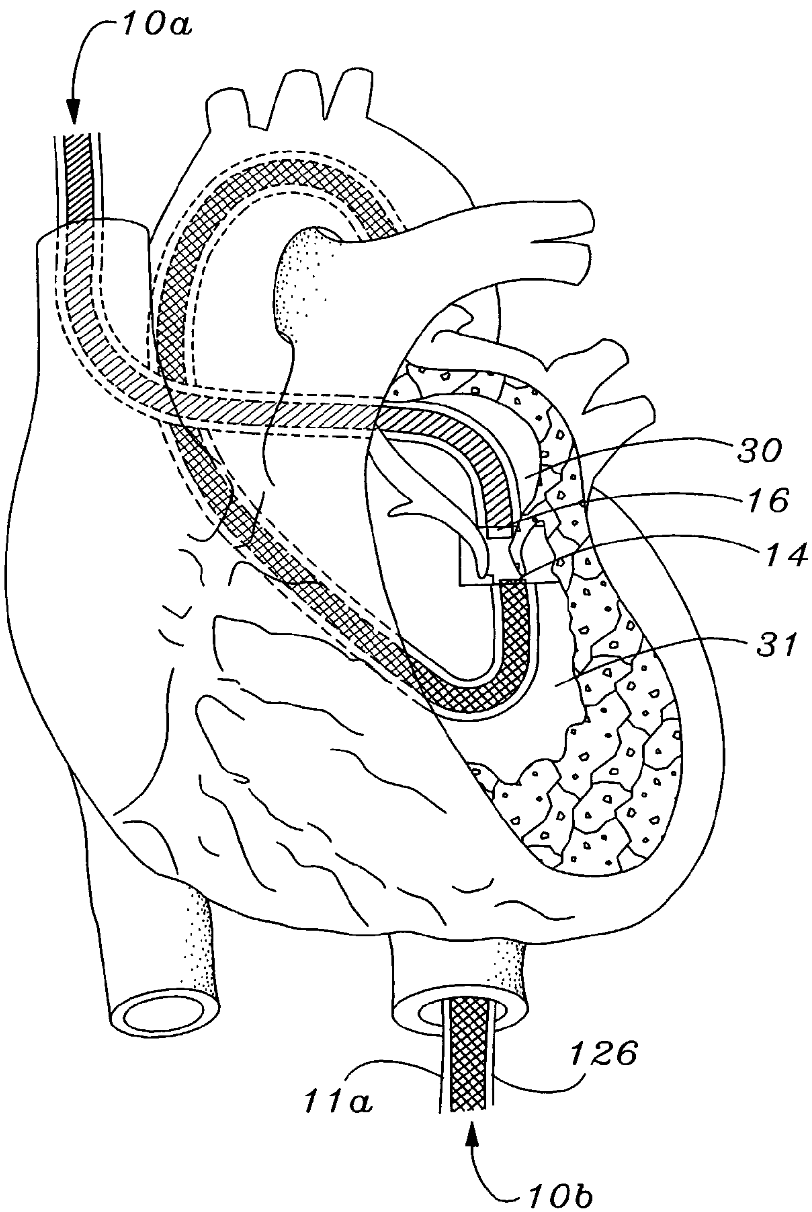
49. The method of claim 38 wherein at least one of said antegrade probe and said retrograde probe is delivered through a brachial artery.

50. The method of claim 38, wherein the tissue comprises arterial septal tissue.

51. The method of claim 38, wherein the tissue comprises ventricular septal tissue.

52. The method of claim 38, wherein the tissue comprises a patent foramen ovale.

Fig. 1



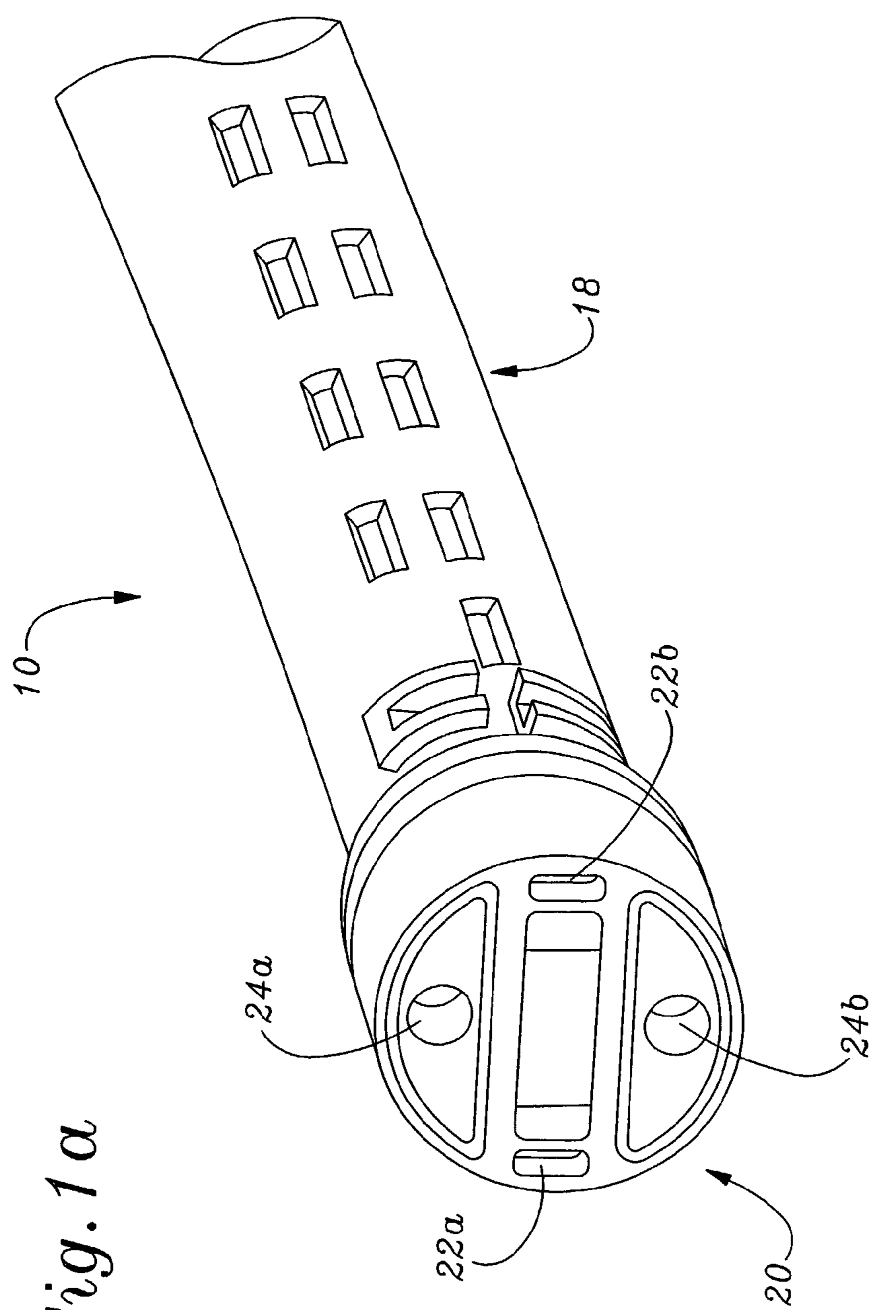


Fig. 1a

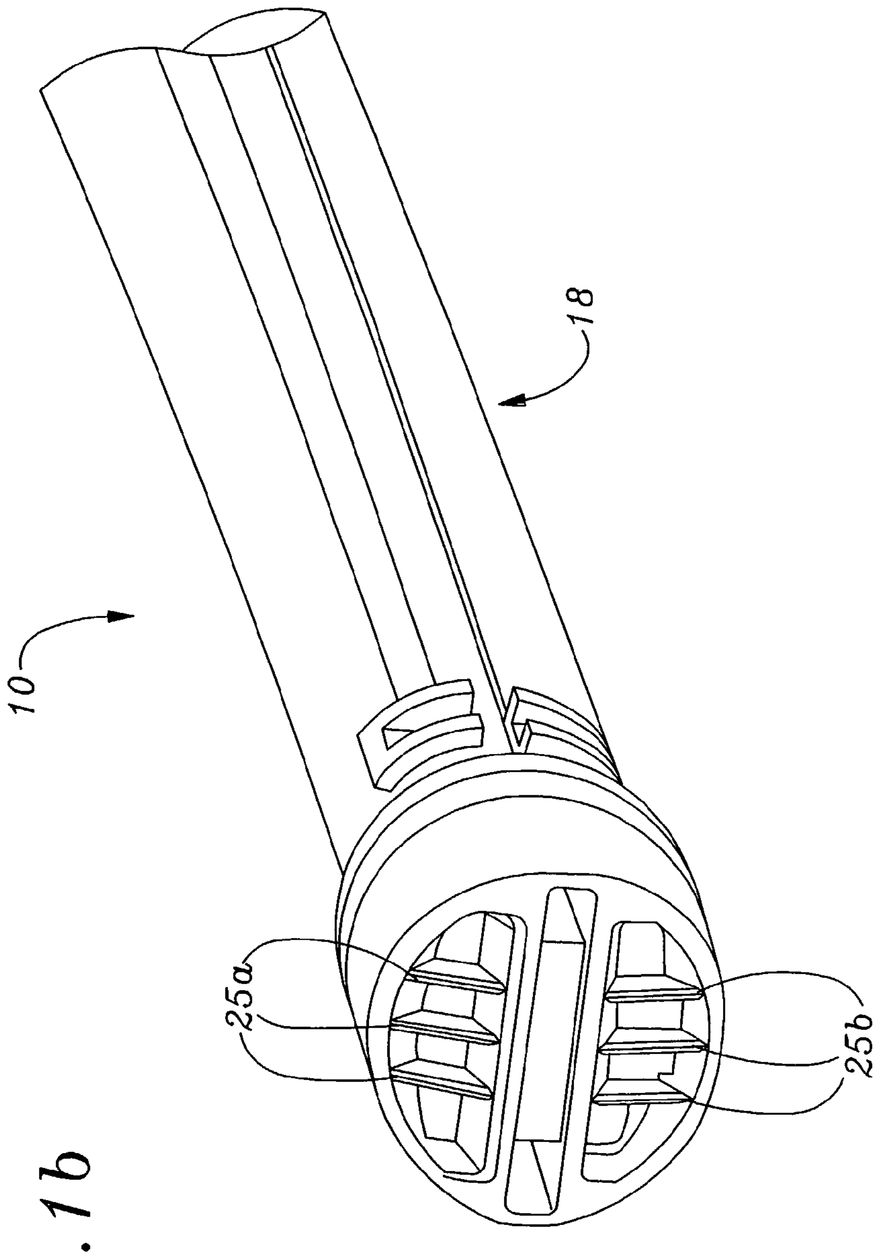


Fig. 1b

Fig.2

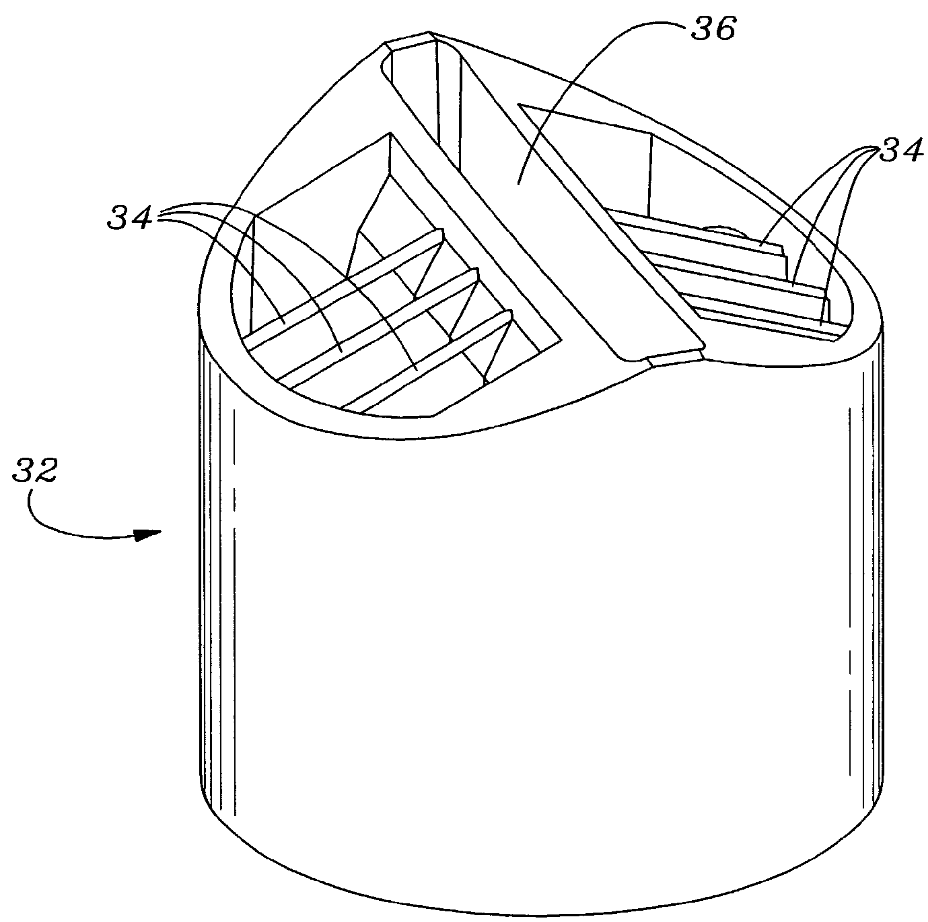


Fig.2a

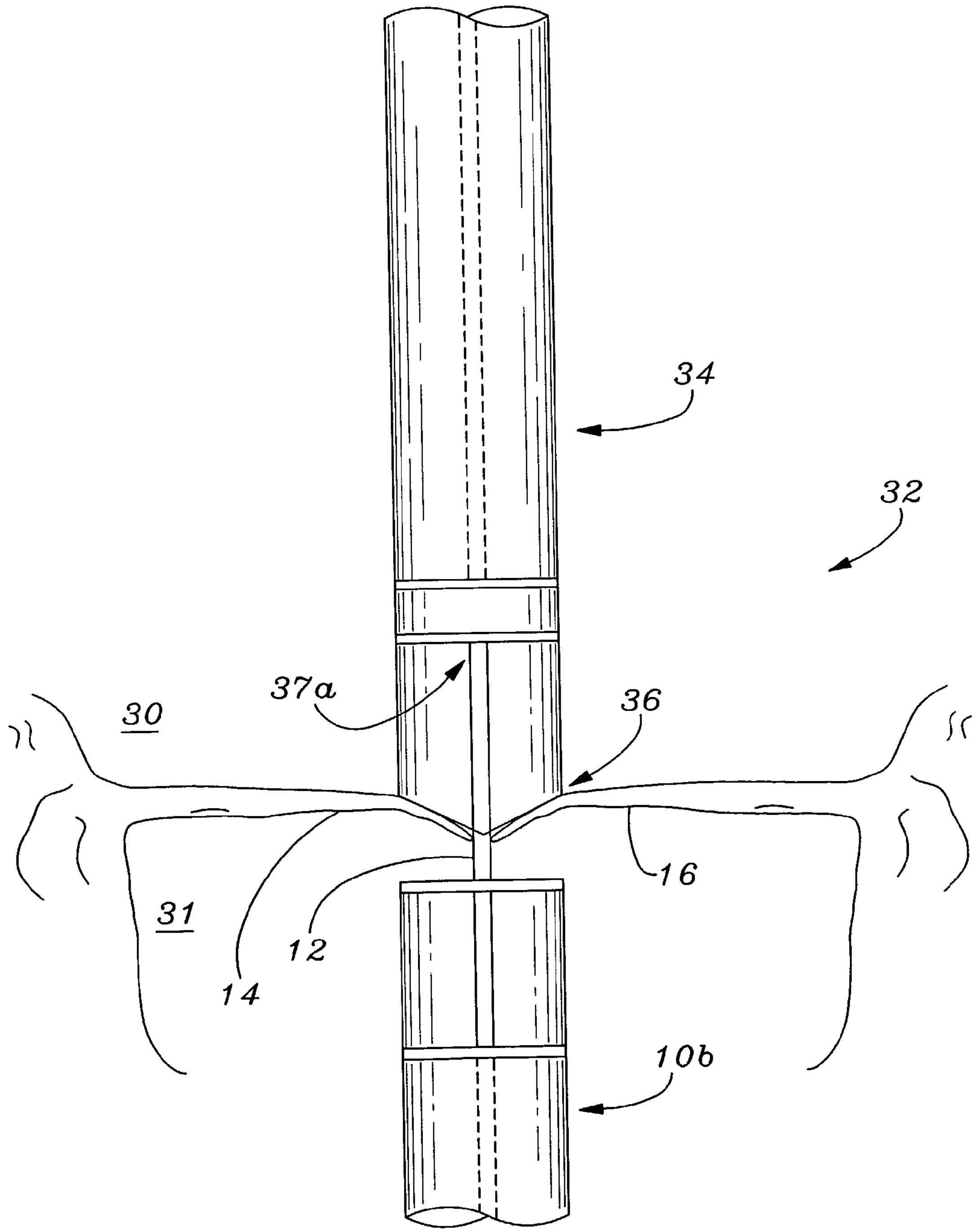


Fig.3a

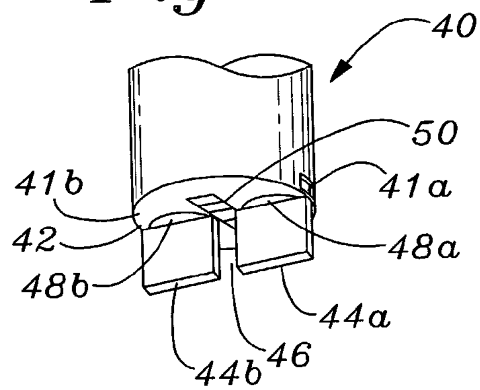


Fig.3b

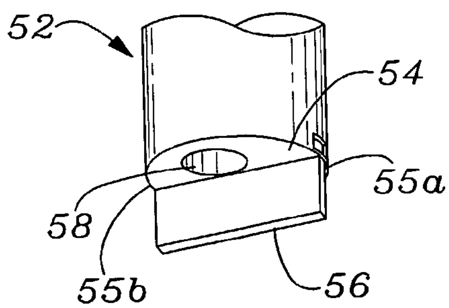


Fig.3c

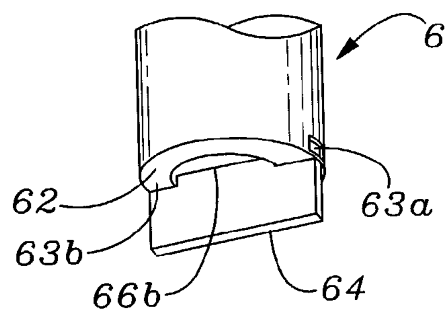


Fig.3d

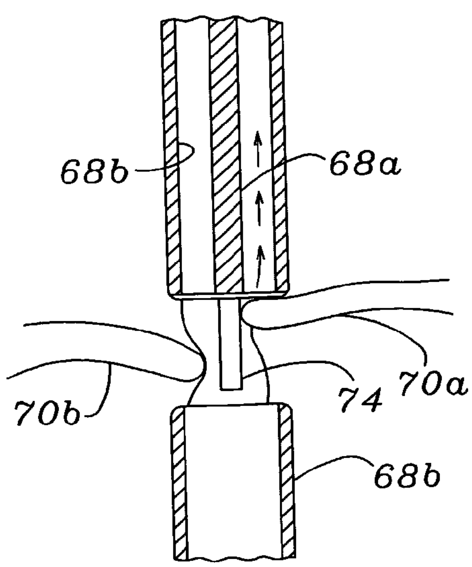


Fig.3e

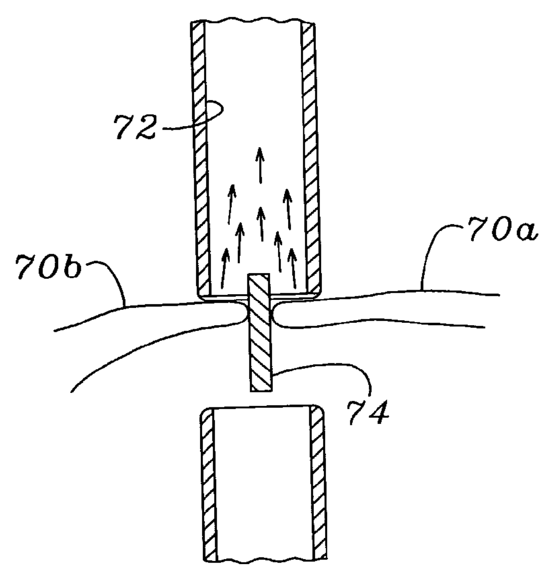


Fig.4a

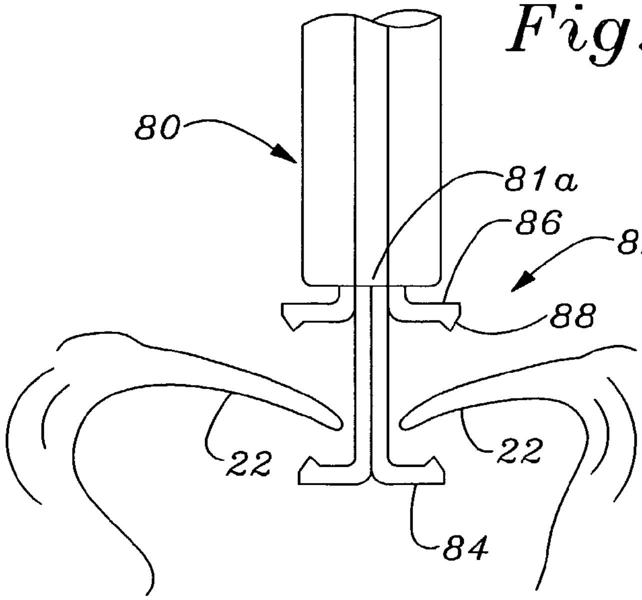


Fig.4b

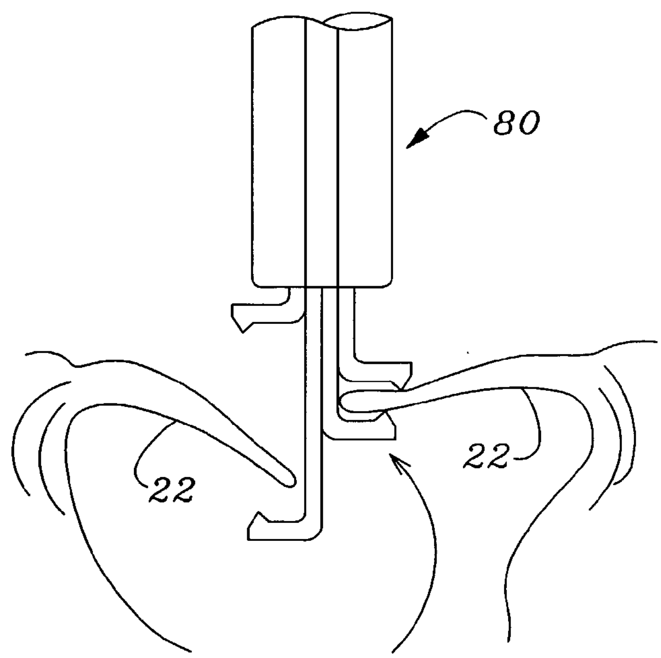


Fig.4c

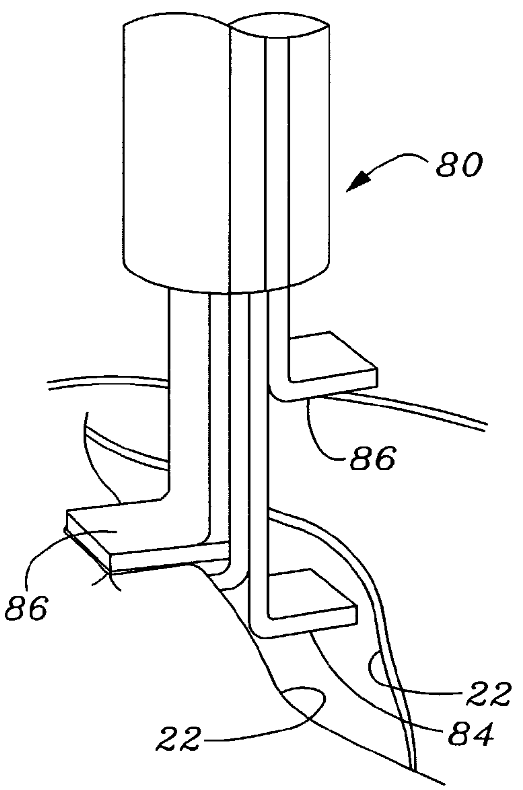


Fig.5b

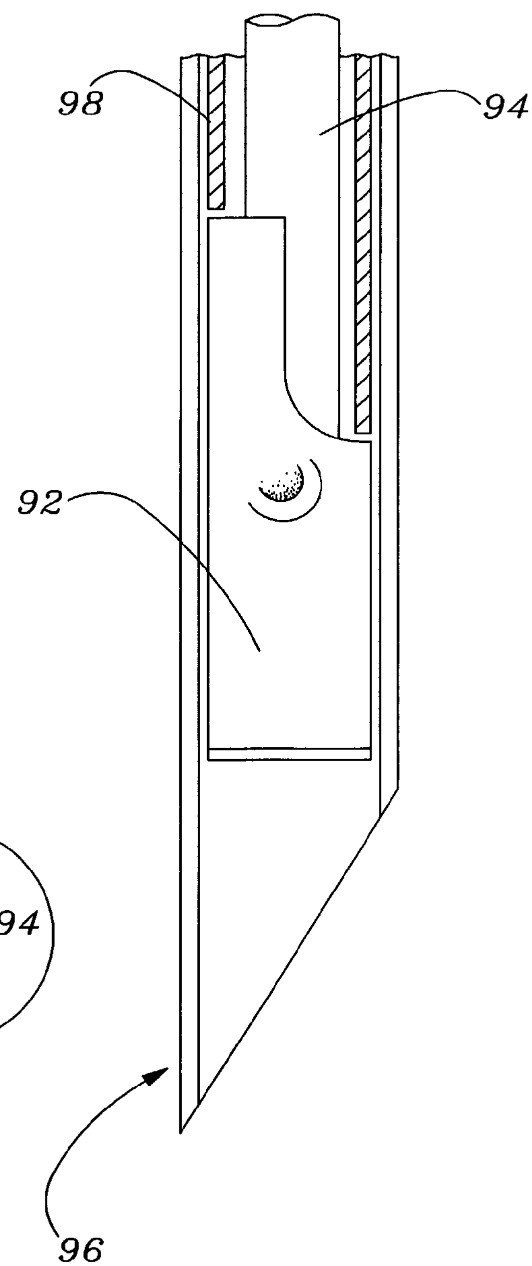
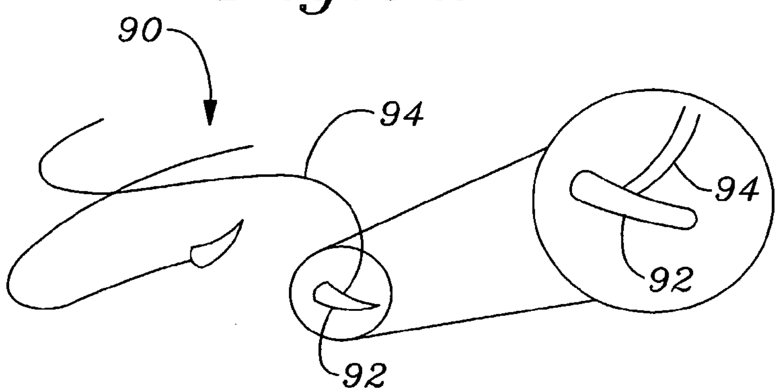


Fig.5a



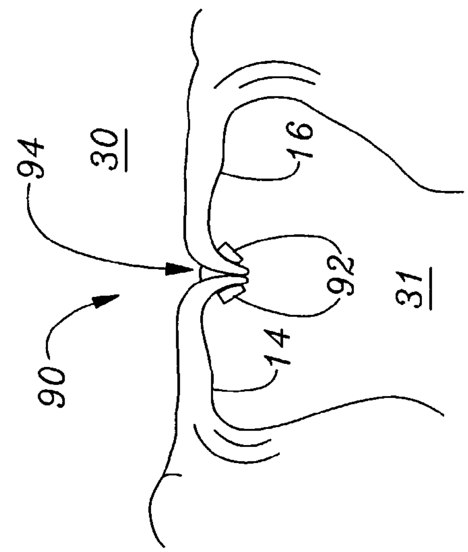


Fig. 6c

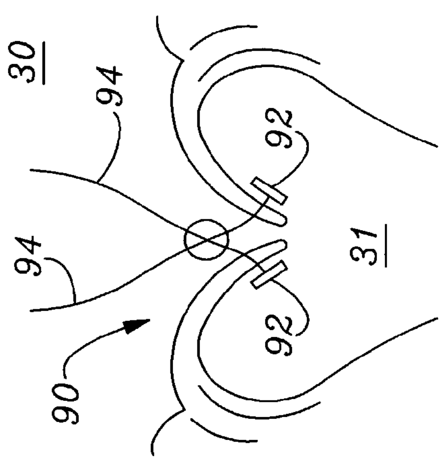


Fig. 6b

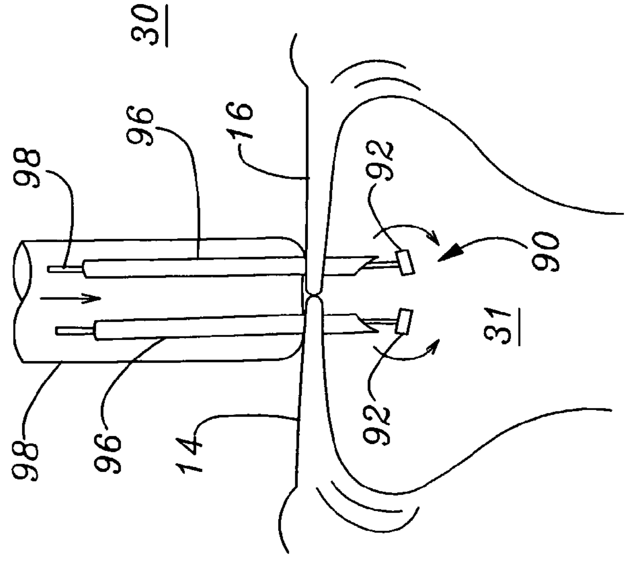


Fig. 6a

Fig. 7

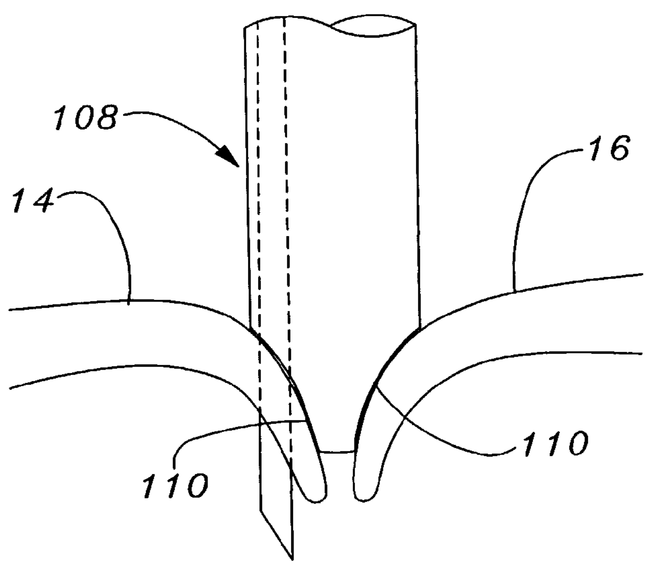


Fig.8A

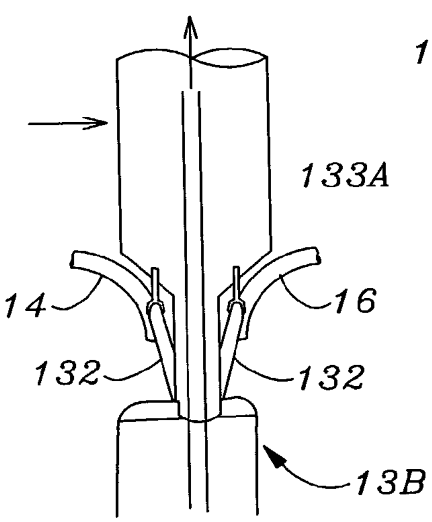


Fig.8B

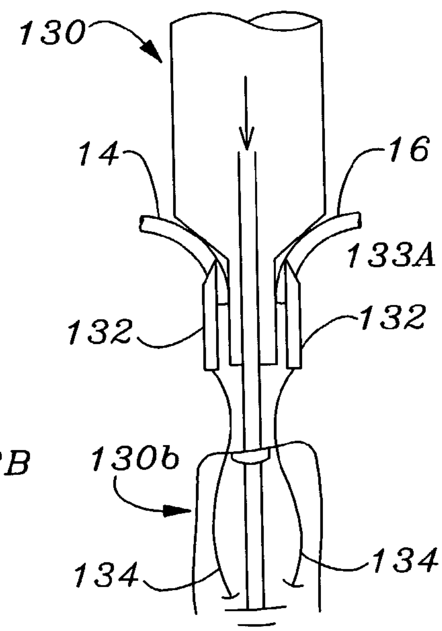


Fig.8C

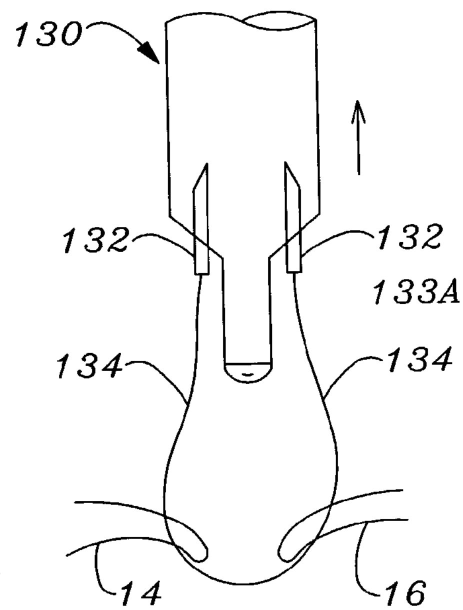


Fig. 10A

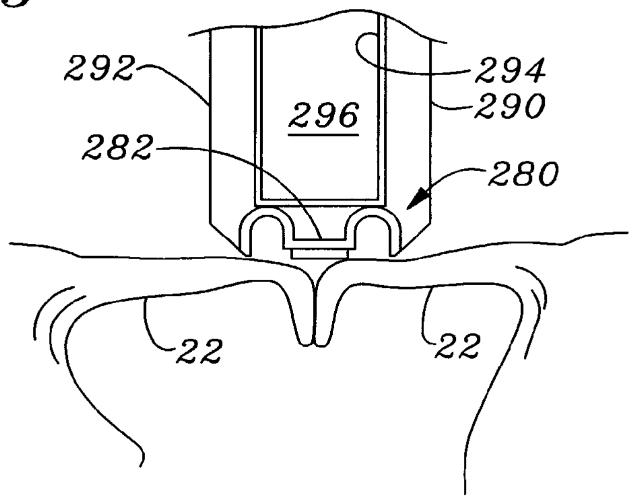


Fig. 9A

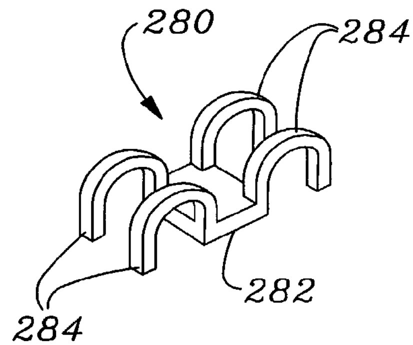


Fig. 10B

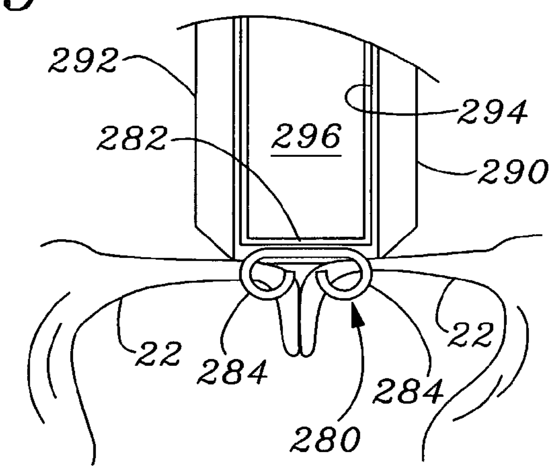


Fig. 9B

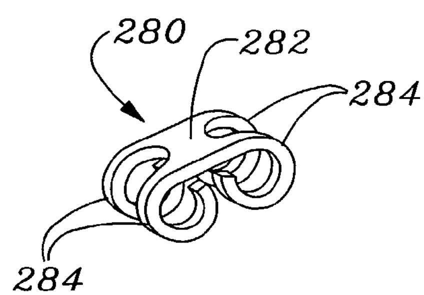


Fig. 10C

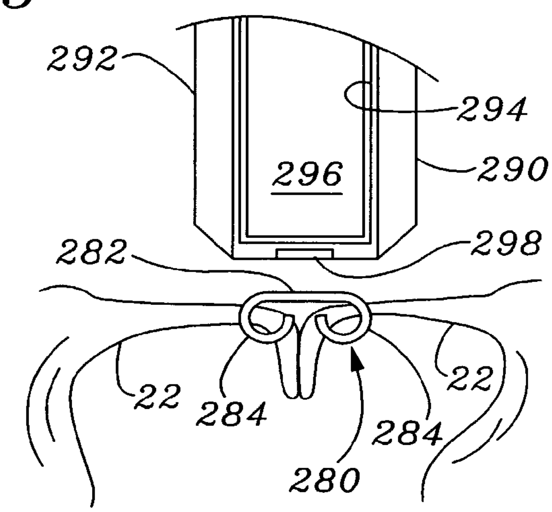


Fig. 11

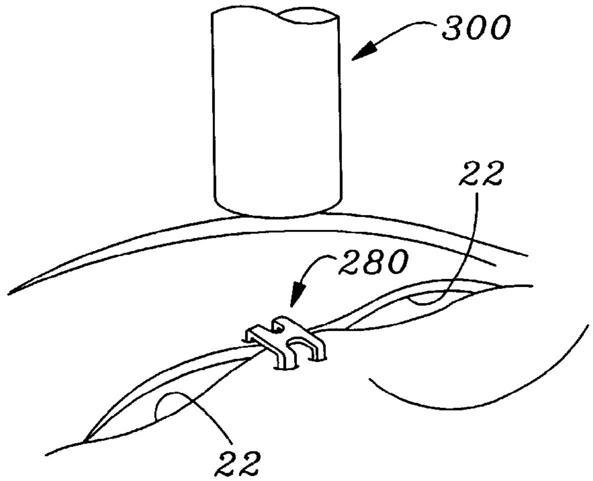


Fig. 12

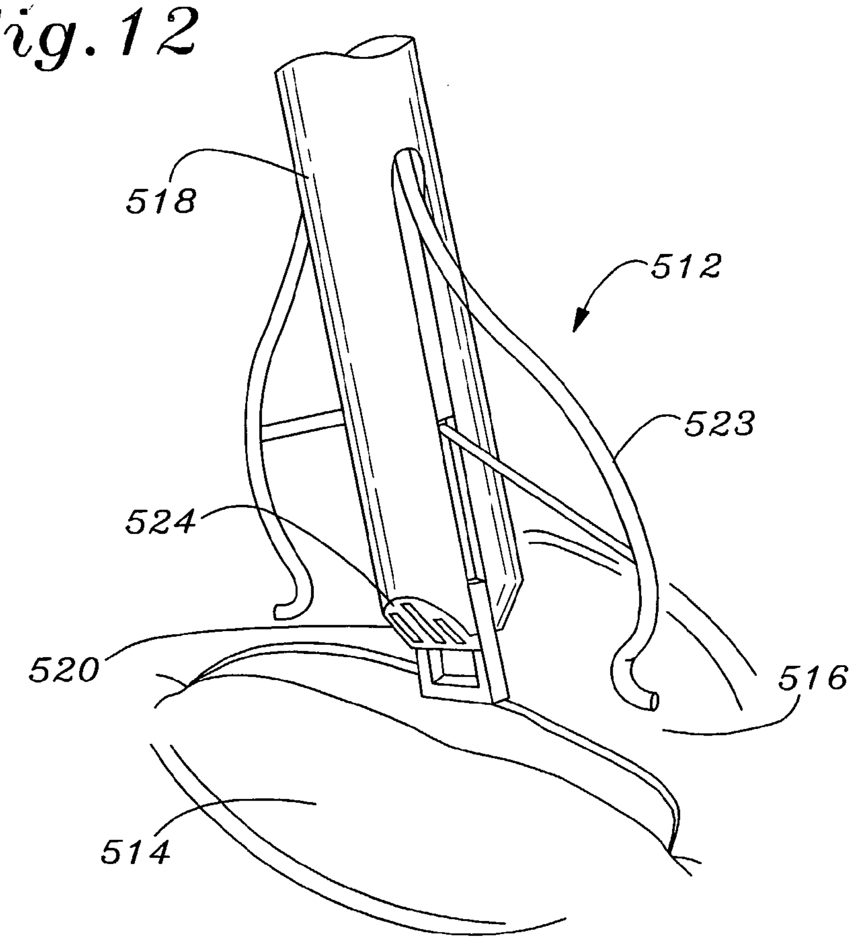


Fig.13A

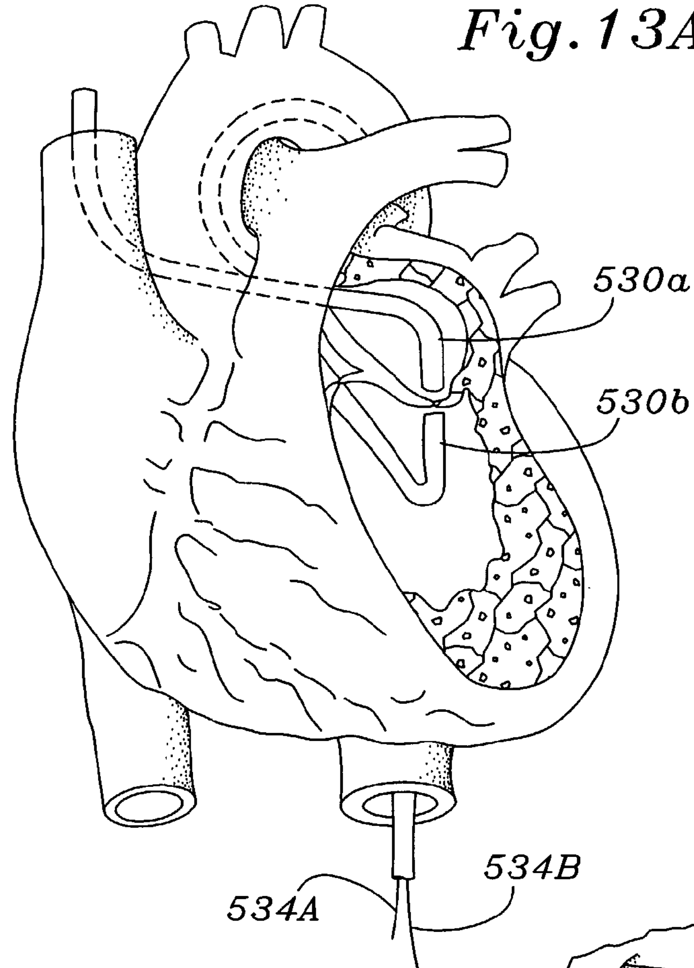


Fig.13B

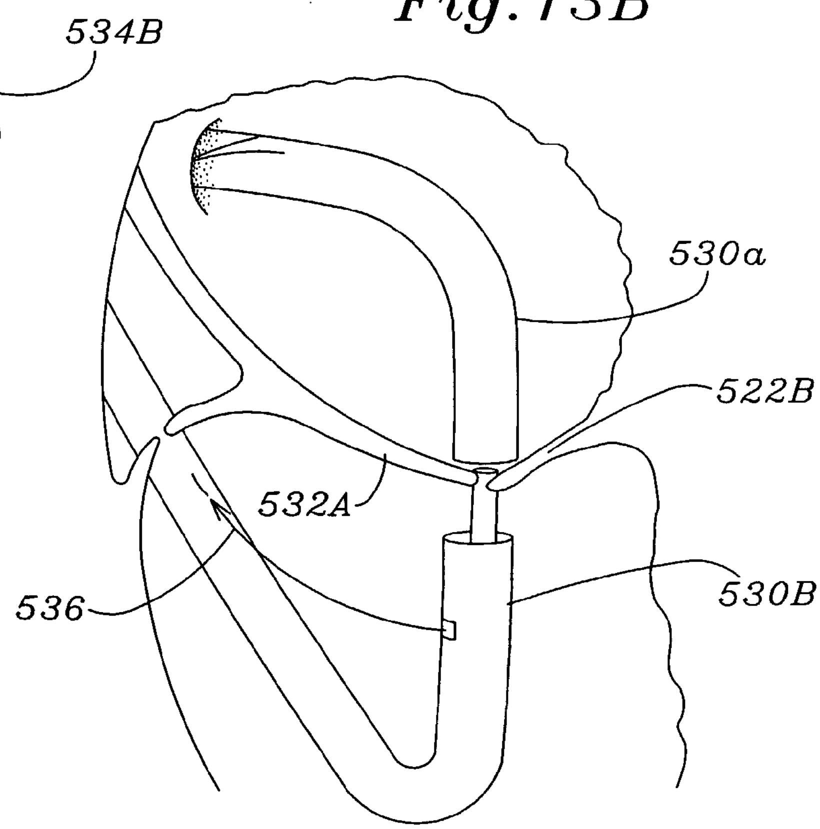


Fig. 14A

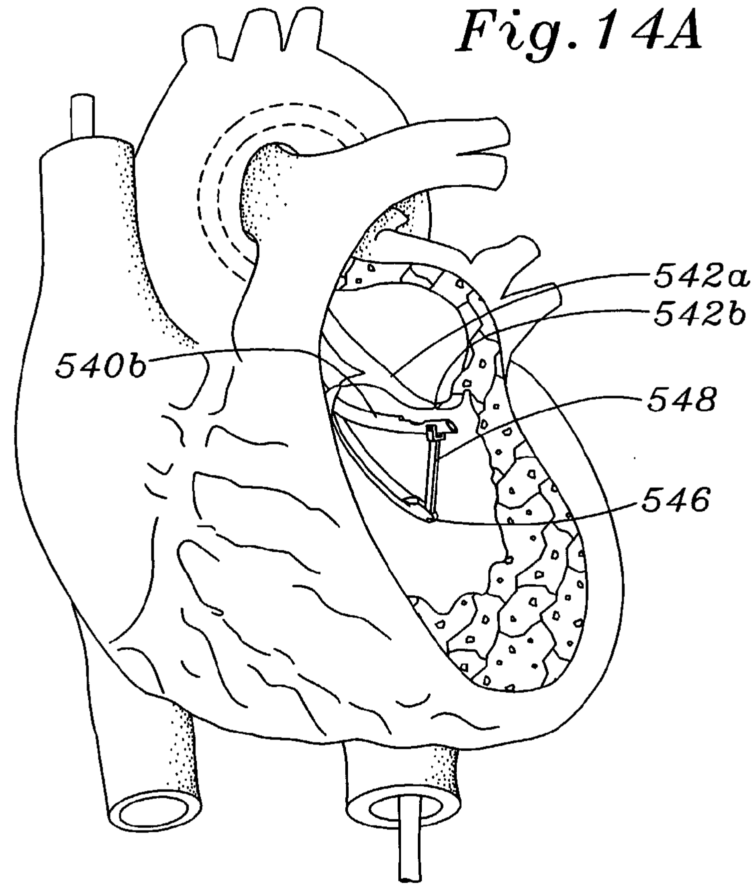


Fig. 14B

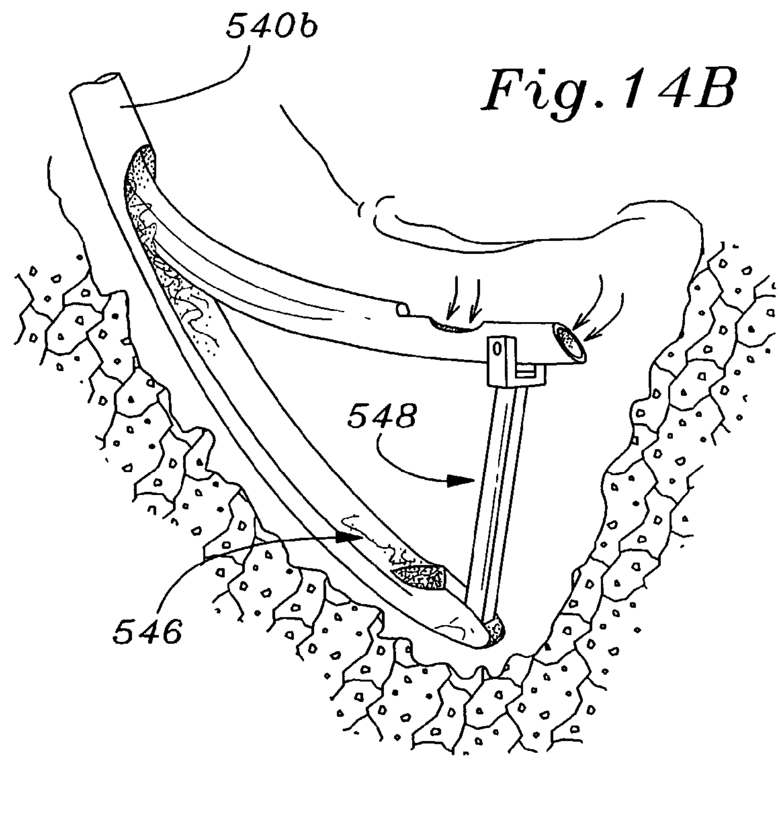


Fig. 15

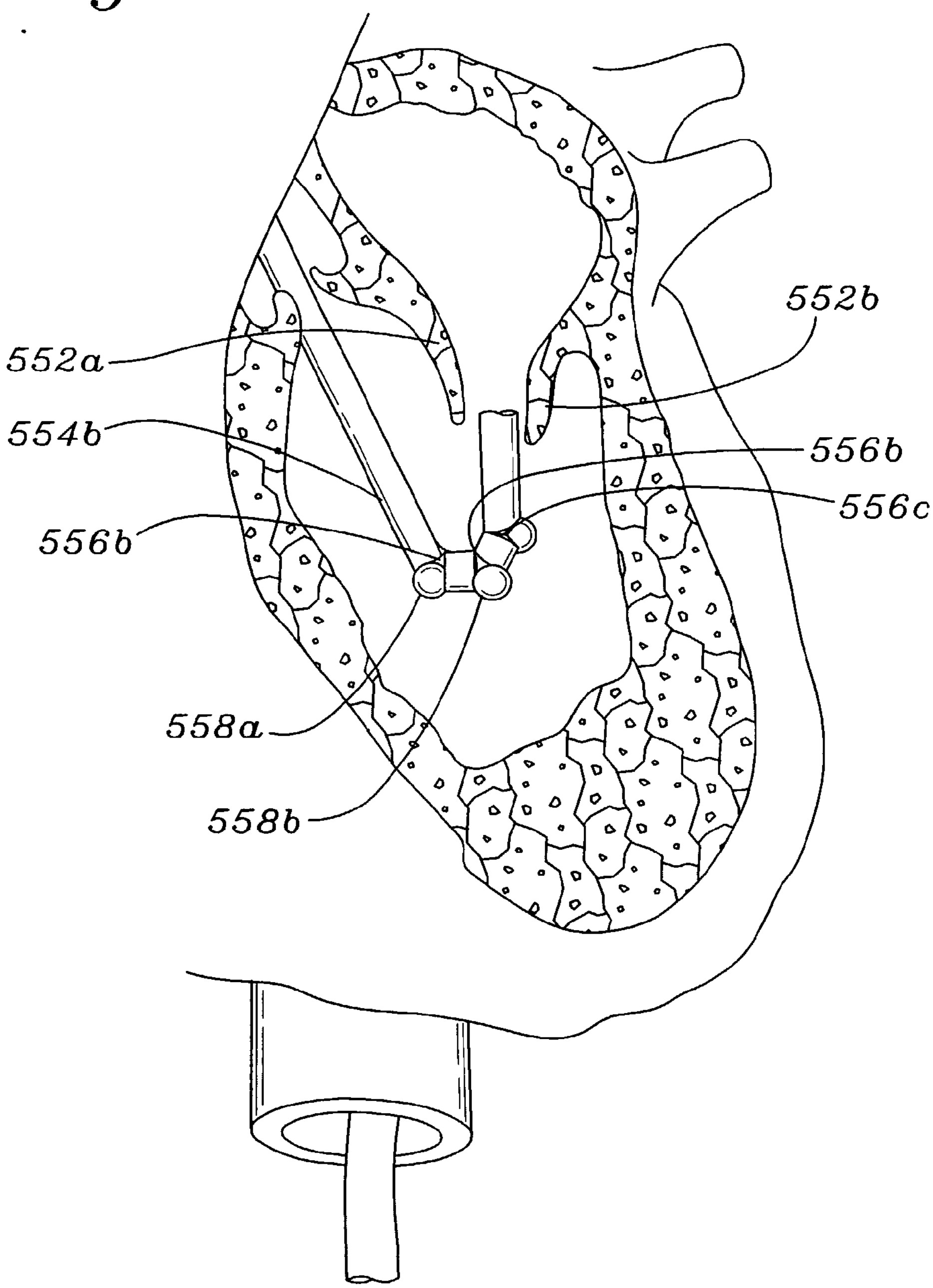


Fig. 16A

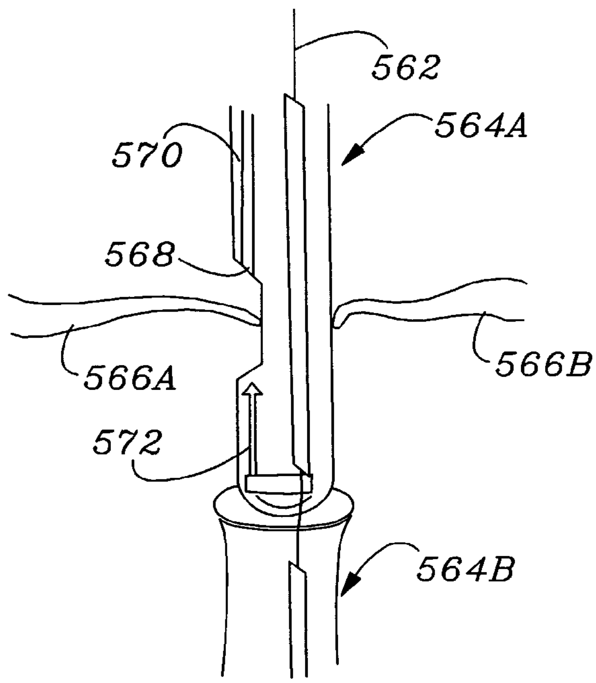


Fig. 16B

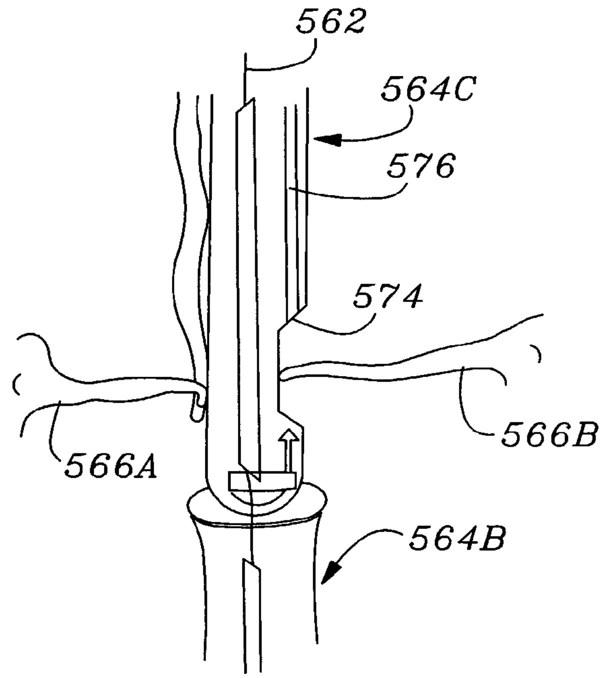
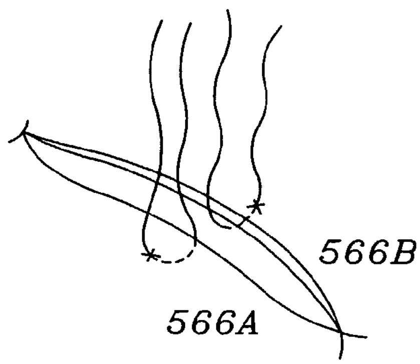


Fig. 16C



INTERNATIONAL SEARCH REPORT

PCT/US 02/03835

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 029 671 A (STEVENS JOHN H ET AL) 29 February 2000 (2000-02-29) column 21, line 50 - line 59 figure 12B	1-23, 26-37
X	US 5 695 457 A (ST GOAR FREDERICK G ET AL) 9 December 1997 (1997-12-09) figure 8	1-23, 26-37
A	US 5 267 958 A (LIEBER GLEN ET AL) 7 December 1993 (1993-12-07) column 14, line 26 - line 33	1-23, 26-37

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 June 2002	28/06/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Bridge, S

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INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 24,25,38-52
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

PCT/US 02/03835

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Information on patent family members

PCT/US 02/03835

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Form PCT/ISA/210 (patent family annex) (July 1992)